Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Investgation of the effect of Curcumin and/or omega-3 polyunsaturated fatty acids supplementation on anthropometric indices, glucose hemostasis, markers of cardiometabolic risk and gene expression of vascular endothelial growth factor and serum concentrations of inflammatory and oxidatve stress indices in type 2 diabetic patients

Protocol summary

Study aim

Determining of the effect of Curcumin and/or omega-3 polyunsaturated fatty acids supplementation on anthropometric indices, glucose hemostasis, markers of cardiometabolic risk and gene expression of vascular endothelial growth factor and serum concentrations of inflammatory and oxidatve stress indices in type 2 diabetic patients

Design

A triple blinded randomized controlled clinical trial with parallel groups

Settings and conduct

This study will be a randomized, triple-blind clinical trial in type 2 diabetes patients in Emam Reza hospital in Tabriz. Participants will be recruited through a convenience sampling and randomly divided into four groups matched based on body mass index, dosage and type of drug. Similar envelopes will be used to conceal the allocation in opaque numbered packages.

Participants/Inclusion and exclusion criteria

Inclusion criteria: > 18 years old, diagnosed as having T2DM based on the criterion of the American Diabetes Association, at least moderately controlled diabetes (%5/8>HbA1c) and a stable anti-diabetic drug regimen (over 4 months) before starting the study Exclusion criteria: Omega 3 fatty acids supplement intake, multivitamin-mineral supplements or medicinal products that interfere with patients' lipid profile, cancer and any chronic disease other than diabetes, pregnancy and lactation

Intervention groups

Intervention group 1: Two 1000 mg omega-3 capsules daily and two 500 mg turmeric capsules for 12 weeks. Intervention group 2: Two 500 mg turmeric capsules and two placebo capsules of Omega 3 containing sunflower oil Intervention group 3: Two 1000 mg omega-3 capsules and 2 capsules of turmeric placebo Intervention group 4 (control): two placebo omega-3 capsules and 2 capsules of turmeric placebo

Main outcome variables

Anthropometric indices, glucose homeostasis, cardiometabolic risk markers and vascular endothelial growth factor gene expression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161022030424N5**
Registration date: **2019-12-02, 1398/09/11**
Registration timing: **prospective**

Last update: **2019-12-02, 1398/09/11**
Update count: **0**

Registration date

2019-12-02, 1398/09/11

Registrant information

Name

Neda Dolatkhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 1928

Email address

dolatkhahn@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2020-08-22, 1399/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investgation of the effect of Curcumin and/or omega-3 polyunsaturated fatty acids supplementation on anthropometric indices, glucose hemostasis, markers of cardiometabolic risk and gene expression of vascular endothelial growth factor and serum concentrations of inflammatory and oxidatve stress indices in type 2 diabetic patients

Public title
Curcumin and/or omega-3 polyunsaturated fatty acids supplementation in diabetes mellitus

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
> 18 years old Diagnosed as having T2DM based on the criterion of the American Diabetes Association At least moderately controlled diabetes (%5/8>HbA1c) A stable anti-diabetic drug regimen (over 4 months) before starting the study

Exclusion criteria:
Omega 3 fatty acids supplement intake Multivitamin-mineral supplements or medicinal products that interfere with patients' lipid profile Cancer and any chronic disease other than diabetes Pregnancy and lactation Smoking Drinking

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
A block randomization method will be used to allocate participants to the groups with a 1:1:1:1 allocation using random allocation software (RAS) with block sizes of 4 and 8. Similar sealed envelopes will be used to conceal the allocation in a sequentially numbered opaque package.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The clinical trial will be triple-blinded and study participants and the trial team/researchers conducting the intervention and assessing the outcomes will be blinded

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave.

City
تبریز

Province
East Azarbaijan

Postal code
3658745698

Approval date
2019-10-24, 1398/08/02

Ethics committee reference number
IR.TBZMED.REC.1398.759

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Anthropometric indices

Timepoint
Measurement of body weight at baseline (before

intervention) and 6 and 12 weeks after omega-3 and / or turmeric supplementation

Method of measurement

Seca digital scale

2

Description

Glucose homeostasis (fasting glucose and insulin concentration)

Timepoint

Measurement of glucose homeostasis at baseline (before intervention) and 12 weeks after omega-3 and / or turmeric supplementation

Method of measurement

Biochemical analysis

3

Description

Cardiometabolic risk markers (triglycerides, total cholesterol, LDL cholesterol, HDL cholesterol and VLDL cholesterol)

Timepoint

Measurement of cardiometabolic risk markers at baseline (before intervention) and 12 weeks after omega-3 and / or turmeric supplementation

Method of measurement

Biochemical analysis

4

Description

Gene expression of vascular endothelial growth factor

Timepoint

Measurement of Gene expression of vascular endothelial growth factor at baseline (before intervention) and 12 weeks after omega-3 and / or turmeric supplementation

Method of measurement

Biochemical analysis

Secondary outcomes

1

Description

Serum concentration of inflammatory indices (hs-CRP)

Timepoint

Measurement the serum levels of inflammatory markers at baseline (before intervention) and 12 weeks after omega-3 and / or turmeric supplementation

Method of measurement

Biochemical analysis

2

Description

Serum concentration of oxidative stress indices (MDA and TAC)

Timepoint

Measurement the serum levels of oxidative stress indices at baseline (before intervention) and 12 weeks after omega-3 and / or turmeric supplementation

Method of measurement

Biochemical analysis

Intervention groups

1

Description

Intervention group 1: Daily intake of two 1000 mg omega-3 capsules (Zahravi pharma co.) and two 500 mg turmeric capsules (made by Dineh Company) for 12 weeks after meals

Category

Treatment - Other

2

Description

Intervention group 2: Daily intake of two 500 mg turmeric capsules (made by Dineh Company) and two omega-3 placebo capsules containing sunflower oil and for 12 weeks after meals

Category

Treatment - Other

3

Description

Intervention group 3: Daily intake of two 1000 mg omega-3 capsules (Zahravi pharma co.) and two turmeric placebop capsules for 12 weeks after meals

Category

Treatment - Other

4

Description

Control group: Daily intake of two turmeric placebo capsules and two omega-3 placebo capsules containing sunflower oil and for 12 weeks after meals

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Neda Dolatkhah

Street address

Emam Reza hospital, Golgasht Str., Azadi Ave., Tabriz

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5163995479

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neda_dolatkhah@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Samiei
Street address
Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave.
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Postal code
6532598756
Phone
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samiei.moh@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Neda Dolatkhah
Position
Assistant professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available